UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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BETH KRAEMER,

Plaintiff,

- against -

SOFIE CO., INC.,

Defendant.

Case No.:

COMPLAINT

PLAINTIFF DEMANDS A TRIAL BY JURY

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Plaintiff Beth Kraemer ("Kraemer" or "plaintiff"), by her attorneys, Vladeck, Raskin & Clark, P.C., complaining of defendant SOFIE Co., Inc. ("defendant," "SOFIE," or the "Company"), alleges:

NATURE OF CLAIMS

1. Kraemer is a 55-year-old nuclear pharmacist with three decades of experience in quality assurance. For nearly seven years, Kraemer worked successfully for defendant SOFIE (and its predecessors, including Zevacor Pharma, Inc. ("Zevacor")), a commercial manufacturer and distributer of radiopharmaceutical drugs, ensuring that drugs released to patients were safe and compliant with FDA and other regulations.

2. On November 29, 2017, SOFIE fired Kraemer after she reported defendant's misconduct that resulted in the release of tainted drugs to Alzheimer's patients in a federally-funded clinical trial in Florida, and other misconduct by SOFIE. Kraemer reasonably believed the reported misconduct violated a law, rule, or regulation, including, inter alia, pervasive practices that violated FDA and state Board of Pharmacy regulations, HIPAA, and federal good manufacturing practice (CGMP) regulations.

3. Kraemer's complaints included significant security breaches in SOFIE's laboratories, including one in Haverhill, Massachusetts, a facility against which the FDA recently issued a "Warning Letter" on September 24, 2018 for SOFIE's "significant violations of current good manufacturing practices" – some of the same violations that Kraemer had reported.[1]

4. In or around May 2017, Kraemer discovered that Zevacor (now SOFIE) had released tainted drugs to Alzheimer's patients; specifically, doses of a radioactive drug used in PET[2] brain scans that contained significant levels of impurities. The results of Kraemer's investigation were reported to regulators. SOFIE was also informed of the drug impurities during pre-acquisition negotiations in summer 2017.

5. Seeking to avoid potential penalties, SOFIE's predecessor Zevacor promised to take substantial remedial action, including firing the supervising pharmacist at the Florida location responsible for the releasing to patients the adulterated drugs, Kirk McCall ("McCall").

6. McCall's quality assurance failures meant that Alzheimer's patients paying exorbitant clinical trial prices were injected with impure, potentially toxic radioactive drugs.

7. Despite McCall's serious misconduct, SOFIE later rehired him in a different state from the Florida location where his glaring regulatory failures caused the release of tainted medicine and were reported.

8. To make matters worse, not long after the official acquisition in September 2017, SOFIE began to dismantle the entire quality assurance team, including by diminishing Kraemer's role and ultimately firing her.

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[1] A copy of the FDA Warning Letter dated September 24, 2018 is attached hereto as Exhibit A.

[2] Positron-emission tomography (PET) is a nuclear medicine imaging technique that is used to observe metabolic processes in the body as an aid to the diagnosis of disease.

9. In addition to reporting defendant's regulatory violations and quality assurance malfeasance, including reports just days before her unlawful firing, Kraemer also made clear to SOFIE her vehement objection to its covert and intentional rehiring of McCall in a state outside of the oversight and jurisdiction of the Florida Board where his malfeasance occurred.

10. Plaintiff brings this action to remedy whistleblower retaliation, in violation of the New Jersey Conscientious Employee Protection Act, N.J.S.A. 34:19-1 et seq. ("CEPA"). Plaintiff further claims defamation under New Jersey common law.

11. Plaintiff seeks compensatory and punitive damages, injunctive and declaratory relief, and appropriate legal and equitable relief.

JURISDICTION AND VENUE

12. This Court has diversity jurisdiction over plaintiff's CEPA claim pursuant to 28 U.S.C. § 1332(a)(i) because the parties are citizens of different states and the amount in controversy exceeds $75,000 exclusive of interest and costs.

13. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because defendant regularly conducts business in New Jersey and a substantial part of the events or omissions giving rise to the claim occurred in New Jersey.

PARTIES

14. Kraemer resides in New York and worked in New Jersey for most of 2017.

15. When SOFIE unlawfully fired Kraemer during a meeting in New Jersey, her title was Director of Pharmacy, Quality Assurance, HD-CO1QA.

16. At all relevant times mentioned herein, defendant SOFIE is and was a Delaware Corporation, doing business in New Jersey, having its principal place of business at 6162 Bristol Parkway, Culver City, California 90230.

17. SOFIE's operational hub is located in Dulles, Virginia.

18. Patrick Phelps ("Phelps") is the President and Chief Executive Officer ("CEO") of SOFIE.

19. Melissa Moore ("Moore") is SOFIE's Chief Technology Officer ("CTO").

20. Throughout her employment, Kraemer often telecommuted from her home in New York, and traveled to defendant's manufacturing sites, including those in New Jersey, New York, Florida, Indiana, Virginia, and Massachusetts.

21. Beginning in or around May 2017 through November 2017 when she was unlawfully fired, Kraemer spent a good portion of her time working at SOFIE's manufacturing sites in Totowa and Somerset, New Jersey.

FACTUAL ALLEGATIONS

Background

22. Beth Kraemer is a licensed nuclear pharmacist in three states[3] with more than 30 years of experience in quality assurance in the pharmaceutical industry.

23. In or around April 2011, SOFIE's then-predecessor company IBA Molecular North America, Inc. ("IBA Molecular" or "IBA") hired Kraemer as a pharmacist; she floated between IBA's Albany, New York and Totowa, New Jersey facilities.

24. In recognition of her accomplishments and her technical, managerial and quality assurance expertise, IBA and later Zevacor promoted Kraemer numerous times.

25. IBA Molecular became Zevacor Pharma, Inc. on or about January 1, 2016.[4]

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[3] Kraemer is licensed in New Jersey, New York and Maryland.

[4] IBA Molecular North America to become Zevacor Pharma, Nov. 30, 2015, available at https://www.prnewswire.com/news-releases/iba-molecular-north-america-to-become-zevacor-pharma-300185284.html.

26. In or around October 2016, Zevacor promoted Kraemer to Director of Technical Development.

27. Zevacor (now SOFIE) is an FDA-registered commercial manufacturer and distributor of radiopharmaceuticals.

28. Radiopharmaceutical drugs carry a degree of radioactivity, which can be used as a diagnostic tool to allow better internal imaging of certain organs and arteries, including the brain.

29. Defendant operates 16 registered radiopharmacies in the United States; 10 sites are also FDA registered and approved radiopharmaceutical manufacturing facilities.

30. During the relevant time period, SOFIE had over 200 employees.

31. Zevacor's Code of Business Conduct and Ethics (the "Policy")[5] prohibits retaliation against an employee who reports suspected violations of the Policy. Employees are required to report any conduct "which is inconsistent with the Company's safety rules, regulations, procedures, and common safe-work practices." The Policy further "requires compliance with all applicable foreign, state and local laws, rules, regulations and ordinances," including, but not limited to, environmental, health and safety laws, antitrust and securities laws, and "federal and state laws governing privacy and Protected Health Information," including HIPAA. Under the Policy, the Company must promptly and impartially investigate complaints of Policy violations, and to keep the reporter's identity confidential to the fullest extent possible.

A. SOFIE Acquires Zevacor

32. SOFIE and Zevacor began negotiating a potential acquisition in or around

[5] Zevacor adopted IBA Molecular's Employee Handbook, which includes the Code of Business Conduct and Ethics which, upon information and belief, SOFIE also adopted after its acquisition of Zevacor in September 2017.

late winter 2017.

33. On April 27, 2017, Kraemer, other members of the Quality Assurance ("QA") team, and Zevacor senior management, attended an introductory transition meeting held by SOFIE. The purpose of the meeting was to identify deficiencies in Zevacor and discuss action plans and assign project leaders so that SOFIE could "hit the ground running" upon its acquisition of Zevacor.

34. The "soft close" for SOFIE's acquisition of Zevacor occurred less than three weeks later, on May 10, 2017.

35. SOFIE announced publicly its intention to purchase Zevacor on May 11, 2017.[6] The sale was effective on September 21, 2017.[7]

36. According to a May 11, 2017 press release,[8] defendant SOFIE "is a developer of molecular imaging diagnostics and technologies to empower widespread access to [PET][,]" including manufacturing the compounds used in PET imaging systems.

37. SOFIE receives substantial federal funding, including a $1.5 million grant award from the National Cancer Institute ("NCI") for its PET imaging technology. SOFIE has stated publicly that the NCI grant will support further development of its products, including PET probes, scanners, and chemistry systems. In an October 2, 2017 presentation made during a meeting that Kraemer attended, SOFIE claimed that it was "[j]ust [a]warded $4M in N[ational] I[nstitute] [of] H[ealth]/NCI grants." In or around October 2018, SOFIE secured

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[6] PR Newswire, Sofie Biosciences To Acquire Zevacor Pharma, May 11, 2017, available at https://www.prnewswire.com/news-releases/sofie-biosciences-to-acquire-zevacor-pharma-300456390.html.

[7] Press Release, Acquisition of Zevacor Pharma Complete, Rebranding as SOFIE, Sept. 27, 2017, available at https://sofie.com/acquisition-zevacor-pharma-complete-rebranding-sofie/.

[8] See n. 6, supra.

from NIH a $5 million grant.[9]

B. SOFIE Is a Contract Manufacturer

38. SOFIE (and before Zevacor/IBA) manufactures in and distributes from its FDA-approved facilities and radiopharmacies radioactive compounds.

39. Defendant also acts as a contract manufacturer for both clinical trial and commercial drug manufacturing, including for Piramal Enterprises ("Piramal").

40. Piramal touts in its 2016-2017 Annual Report[10] to investors that it has nine FDA-approved pharmaceutical manufacturing facilities in the U.S., all of which are owned and operated by SOFIE, Piramal's contract manufacturer.

41. Piramal assures investors ("Strong focus on compliance, quality and reliability") that its FDA-approved facilities have an "excellent track record," with "[n]o instance of halting production or any negative publicity due to issues raised by the US FDA or other regulatory authorities."

42. Piramal Imaging, a subsidiary of Piramal Enterprises, is the patent-holder for an FDA-approved radioactive tracer drug called Neuraceq™ (Florbetaben) (referred to as "Neuraceq," "Neuraceq/FBB," or "FBB").[11] Piramal in its 2014-2015 Annual Report to shareholders described Neuraceq as the company's "promising lead commercial stage product[,]"

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[9] See https://www.dotmed.com/news/story/44709.

[10] Piramal Enterprises Ltd. 2016-2017 Annual Report, available at http://piramal.com/assets/pdf/financial_annual_reports/Piramal-AR2017-Final-For-Web.pdf.

[11] The FDA approved Piramal's New Drug Application for Neuraceq/FBB, albeit for limited forms of treatment, in March 2014. See https://www.prnewswire.com/news-releases/fda-approves-piramal-imagings-neuraceq-florbetaben-f18-injection-for-pet-imaging-of-beta-myloid-neuritic-plaques-in-the-brain-251216031.html. Upon information and belief, Piramal spent millions of dollars to bring FBB to market.

and "the lead compound that is used in the detection of Alzheimer's disease."[12]

43. When used with PET scanning to create an image of a patient's brain, Neuraceq/FBB can reveal the presence or absence of sticky clumps of protein (called β-amyloid plaque) that form in the brains of people who have Alzheimer's disease and other causes of cognitive decline.[13]

44. Administering to patients radioactive drug Neuraceq/FBB is not without risks, and thus compliance with manufacturer and state and federal regulations is critical. "[S]imilar to other radiopharmaceuticals, [administration of Neuraceq/FBB] contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer."[14]

45. SOFIE by contract with Piramal manufactures and distributes FBB, including for clinical PET programs focused on neurologic diseases, such as Alzheimer's. SOFIE/Zevacor's contractor arrangement with Piramal is governed by at least two contracts: an International Manufacturing Agreement and a Quality Assurance Agreement (the "QA Agreement").

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[12] Piramal Enterprises Ltd. 2014-2015 Annual Report, available at http://piramal.com /assets/pdf/financial_annual_reports/AR_2015a.pdf. Piramal in that Report further states, "The Company's Imaging business . . . is well positioned to become a market leader in molecular imaging. The potential size of the market could be in multi-billion dollars. Its promising lead commercial stage product, NeuraCeq (INN: Florbetaben), which received approvals from the USFDA and European Commission in FY2014, has commenced its commercial sales during this financial year."

[13] http://www.piramal.com/neuraceq/main.php?s=pa#neuraceq-pet-scan.

[14] PR Newswire, Piramal Imaging to Present New Research in PET Imaging at CTAD Annual Meeting, Nov. 1, 2017, available at http://piramal.com/assets/pdf/press_releases/CTAD_2017 _Curtain_Press_Release_-_for_IRC_reveiw.pdf.

46. Under the QA Agreement, SOFIE/Zevacor's manufacturing operations must be carried out according to all agreed-upon requirements in that Agreement, the Manufacturing Agreement, and all applicable regulatory requirements. Under the QA Agreement, Piramal has an unconditional right to review any communication related to products SOFIE manufactures before such communication is submitted to the FDA or other regulators.

47. Kraemer served as the Neuraceq/FBB Project QA from the start of the contract manufacturing of FBB by IBA Molecular in January 2012.

Kraemer Discovers Bad Batches of FBB Manufactured in Sanford, Florida

48. Just days after the "soft close" in the spring of 2017, Kraemer received reports of impurities far exceeding acceptable limits, which can be toxic to patients, that had been detected in SOFIE's second largest contract manufacturing site in Sanford, Florida.

49. Specifically, on May 15, 2017, Kraemer, who was working on-site at defendant's Totowa, New Jersey facility, received an email from Priscilla Caro ("Caro"), the QA specialist in defendant's Sanford facility. Caro told Kraemer that a stability test on Neuraceq/FBB had failed. Caro reported FBB impurities that exceeded the acceptable limit seven times over. FBB impurities that exceed certain thresholds can be harmful to patients.

50. Kraemer immediately commenced an inquiry, which included requesting all recent FBB batch records; High Performance Liquid Chromatography ("HPLC") analytical test results, testing which is essential for accurate impurity level determinations; and pharmacy records of patient doses dispensed from the Sanford facility.

A. Kraemer Discovers and Reports Lapsed Oversight by Pharmacist Kirk McCall

51. McCall was the supervising pharmacist (also known as the Prescription Department Manager ("PDM") in the State of Florida), site manager and Quality Assurance Officer ("QAO") for the Sanford, Florida facility.

52. Under the Florida Administrative Code, the PDM is legally responsible for all pharmacy personnel and activities, including, but not limited to, proper dispensing of prescriptions drugs; ensuring such drugs are not adulterated or misbranded; training pharmacy employees; ensuring adherence to all federal and state regulations; and otherwise having substantial knowledge and background in QA.

53. McCall's QA track record had been an ongoing concern for Kraemer.

54. When Kraemer started working at IBA as a floating pharmacist, she reported to McCall for approximately six months. At the time, McCall was the Regional Operational Director for IBA's Albany, New York facility. When mold was discovered in that facility's sterile lab – a significant regulatory violation – McCall proposed as a "remedial action" simply painting over the toxic mold. Kraemer reported this serious problem to IBA's quality team; thankfully the team intervened, closing the plant for mold remediation and halting operations and dispensing until the lab was safe.

55. In 2015, Kraemer discovered that McCall had diluted FBB into compliance in an attempt to correct a high impurity profile; the diluted FBB was dispensed to patients participating in a federally-funded clinical trial. FBB should never be diluted. Indeed, the further dilution of the final drug product Neuraceq™-FBB is expressly prohibited in Piramal's New Drug Application ("NDA") to the FDA. (See n.11, supra).

56. When Kraemer confronted McCall, he admitted to diluting the batch, and confirmed that the doses from the non-compliant batch had been dispensed to clinical trial patients. Kraemer notified Zevacor management and Human Resources ("HR"), and Piramal, about the diluted batch and dispensed doses.

57. On information and belief, the 2015 incident was not reported to regulators and no remedial action was taken against McCall or otherwise. Kraemer however kept detailed records of the incident, with copies also placed in Sanford QA files, to ensure that the FDA would have access to such records during future audits and inspections at the Sanford facility.

58. On or about April 15, 2015, Piramal and others applied for federal funding for a clinical trial called the "Imaging Dementia – Evidence for Amyloid Scanning (IDEAS) Study." The IDEAS Study Details state,

> The IDEAS Study is an observational, open-label, longitudinal cohort study designed to assess the impact of amyloid PET on patient-oriented outcomes in Medicare beneficiaries with mild cognitive impairment (MCI) or dementia of uncertain etiology. The study falls under the Centers for Medicare & Medicaid Services (CMS) Coverage with Evidence Development (CED) policy. A total of 18,488 Medicare beneficiaries meeting Appropriate Use Criteria (AUC) for amyloid PET will be enrolled over 24 months at sites throughout the United States. Dementia specialists will team with PET facilities able to perform amyloid PET and with trained radiologists/nuclear medicine physicians, all of whom will consent to completing the data requirements and timelines for the study. Amyloid PET will be performed and interpreted at each facility with results provided to the ordering physician for support in further clinical decision making, which will be captured for the study. Our over-arching hypothesis is that, in diagnostically uncertain cases, knowledge of amyloid status as determined by amyloid PET will lead to significant changes in patient management, and that this will translate into improved long-term outcomes.

The IDEAS study participants must be Medicare beneficiaries diagnosed with MCI (mild cognitive impairment) or dementia. Piramal's FBB is one of the drugs to be tested in the IDEAS clinical trial.

59. The commercial price of FBB is government regulated. If used for an indication stated in the New Drug Application to the FDA, Piramal can charge a patient no more than approximately $150 per dose. However, if used in the IDEAS clinical trial, Piramal is not bound by the government-mandated price-per-dose. Indeed, Piramal in the IDEAS clinical trial charges approximately $5,000 per dose and pays SOFIE/Zevacor approximately $400 per dose (plus a dispensing fee).

60. Nearly all of the doses of FBB manufactured in the Sanford, Florida facility that contained the impurities were prescribed and dispensed to IDEAS clinical trial patients paying top dollar for the drug.

61. After QA specialist Caro's May 15, 2017 email reporting the potentially toxic dosages, Kraemer asked Frank Valla ("Valla"), Zevacor's Product Development Specialist, to double-check the results for the FBB impurity tests at defendant's eight other FBB manufacturing facilities. Valla determined that the impurity issue was limited to the Sanford facility where McCall was the supervising pharmacist/QAO/PDM.

62. After reviewing the Sanford FBB data dating back to December 2016, Valla discovered that defendant had released 15 batches and dispensed over 30 patient doses from the batches of FBB with non-compliant impurity levels.

63. In accordance with its QA Agreement with Piramal, on May 17, 2017, Zevacor notified Piramal of the FBB impurity issue. Zevacor and Piramal participated in a conference call the following day during which they discussed a Plan of Action, including that Kraemer would oversee dispensing of doses and review all FBB batches from the Sanford facility before they were sent to patients.

64. On May 23, 2017, Kraemer; two members of Zevacor's Technical Development team, Valla, and Norbert Owino ("Owino"); and Henry Mok ("Mok") from Piramal's Chemistry, Manufacturing, Controls ("CMC") department, went to SOFIE/Zevacor's Sanford facility to further investigate how the FBB batches and doses came to contain impurities, and how the impurities were not discovered before the drugs were dispensed to clinical trial patients. The QA and CMC team's on-site visit lasted three days.

65. During the QA investigation, Kraemer and her team discovered other QA infractions.

66. First, volumes of FBB greater than the FDA-approved 10 mL had been dispensed to clinical trial patients. Calculations for the acceptable impurity profile for FBB are based on a maximum volume of 10mL, and is in Piramal's NDA as a mandatory dose release criterium.

67. Secondly, 50 mL vials were being used instead of the FDA-approved and validated 30 mL vials. The process and stability studies for Piramal's NDA for FBB and the Container Closure Integrity Testing were performed only in 30 mL vials, not 50 mL. If a 50 mL vial is used, it would require a Post-Approval Submission to the FDA, and necessitate a repeat of the process and stability validation work.

68. Kraemer also uncovered additional significant compliance failures by supervising pharmacist McCall. For example, for at least six months, McCall had failed to review High Performance Liquid Chromatography (HPLC) calibration curves, testing which is essential for accurate impurity level determinations.

B. Zevacor Informs SOFIE, Piramal and the Florida Board of Pharmacy

69. During a June 9, 2017 meeting, Zevacor notified SOFIE about the impure batches and its ongoing QA investigation. Zevacor President Peter Webner ("Webner"); Zevacor Chief Operating Officer ("COO"), Anthony Stagnolia ("Stagnolia"); Zevacor Head of QA/RA/EHS Jill Wilson ("Wilson"); SOFIE CTO Moore; and SOFIE President and CEO Phelps attended the meeting. Webner told SOFIE that there had been an incident at Zevacor's Sanford facility in which batches with high dose impurities of FBB were released to clinical trial patients over an extended period. Webner also told SOFIE that McCall, the supervising pharmacist/QAO/PDM responsible for the adulterated batches, was going to be fired.

70. During the June 9, 2017 meeting, Moore asked permission to notify her soon-to-be Regional Directors ("RDs") about McCall's dismissal. At the time, McCall was slated to be one of Moore's top RDs when SOFIE took over. Webner said that McCall had not yet been told about his firing and asked that Moore not disclose this information until the termination of McCall's employment was finalized.

71. Zevacor issued its internal QA report a week later.[15] The June 16, 2017 report states, in relevant part (emphasis added),

> A review of the items that fall under practice of pharmacy showed multiple deficiencies. There was a failure on the part of the pharmacists certifying the release of the batch and dispensing the doses to perform the necessary pharmaceutical calculations as it relates to the single largest unspecified dose impurity. This was further certified on the batch record by the pharmacist that each of the individual doses met this specification. Had the calculations been performed, these doses would not have been released for patient use. . . . These deficiencies are viewed to be chronic and egregious due to the frequency and duration of occurrence.

[15] Kraemer's colleague Wilson wrote and signed the internal report.

* * *

> The pharmacists falsely certified and signed that the calculations were performed and that all the doses were within specification. This occurred multiple times over the course of a six-month period (this investigation included December 2016 through May 2017).

72. On June 22, 2017, Zevacor sent Piramal a copy of the June 16, 2017 internal report. Exercising its authority under the QA Agreement, Piramal instructed Zevacor not to report the issues to the FDA.

73. Zevacor fired McCall on June 23, 2017. On information and belief, Zevacor's COO Stagnolia and Zevacor HR Director, Robbie Smith ("Smith"), attended the firing meeting.

74. On June 26, 2017, per Piramal's instruction, Zevacor reported the Sanford impurity issue to the Florida Board of Pharmacy. As to the remedial action Zevacor promised to take, the letter stated, in relevant part (emphasis added):

> These deficiencies are viewed to be chronic and egregious due to the frequency and duration of occurrence. As a result, one of the pharmacists involved, Kirk McCall, is no longer with the company. The other two [pharmacists] continue to work at Zevacor's Sanford facility under strict oversight by another nuclear pharmacist [Kraemer] and corporate representative. This structure will remain in place pending any Board action. These actions are not ones that were or will ever be condoned by Zevacor's quality procedures/policies or management philosophies on pharmacist's professional conduct. As the time this was discovered, Zevacor's COO (Chief Operating Officer) Anthony Stagnolia and Interim Head, QA/RA/EH&S Jill Wilson sent out a memorandum requiring all batches of FBB dispensed out of the Sanford facility to be co-released by Beth Kraemer, RPh (Nuclear Pharmacist), Director of Technical Development, who also later traveled to the Sanford facility and retrained the two remaining pharmacists. Zevacor would like to maintain this standard of care, until it has been established that the facility employees understand the requirements and procedures necessary to properly release doses of FBB for patient use.
>
> Zevacor also wants to bring in better site-level management to remediate the issues that have been discussed above. As such, future changes in the prescription

> department manager may be required based on further root cause analysis.
>
> Conclusion
>
> Zevacor constantly strives to produce and deliver a superior, quality radiopharmaceutical product that is both safe and effective for the patients. Following the discovery and investigation of this incident, Zevacor cannot condone the behavior that is not in line or reflect[ive of] Zevacor's core values and policies. Zevacor is doing everything in its power to remedy the situation and prevent future reoccurrence.

75. On August 21, 2017, Zevacor sent a second letter to the Florida Board of Pharmacy. Zevacor informed the Board that it had further investigated the FBB patient dose information from the Sanford facility, including extending its investigation to review information going back to January 1, 2016, "the full time period of the clinical trial the[] doses were from."

76. The August 21 report states, "It was discovered that six more doses of FBB had been released with higher than allowable single dose impurities[,]" raising the total affected patient count to nearly 40. Zevacor assured the Board of Pharmacy that the two remaining employees responsible for the impurities had been retrained by Kraemer, and reiterated that, going forward, all Sanford batches would be reviewed and co-released by plaintiff. The report concludes,

> As previously stated in our last letter, Zevacor strives to release radiopharmaceuticals which are safe and effective. Zevacor has conducted significant site remediation of our Sanford, Florida facility to ensure these types of errors do not occur going forward. These modifications include changes to site-level management and strict corporate oversight and reporting. Safeguards are now in place to ensure that errors like this do not happen again.

77. SOFIE's acquisition of Zevacor was official a month later, on September 21, 2017.

D. SOFIE Covers-up the Regulatory Failures and Dismantles the QA Team

78. Shortly after the September 2017 takeover and in the months leading up to it, SOFIE commenced a cover-up of the Sanford facility regulatory failures and reversed the steps

Zevacor had taken to remedy the problem and assure future compliance. Indeed, SOFIE did not honor any of the promises and assurances Zevacor had made to the Florida Board of Pharmacy.

79. For example, between McCall's October 11 rehire and Kraemer's unlawful dismissal on November 29, 2017, contrary to the representations to the Board of Pharmacy, SOFIE did not make any effort to retrain McCall on proper FBB batch release and dispensing procedures.

80. To make matters worse, even before the acquisition was official, SOFIE began disbanding Zevacor's QA team, without filling the empty positions or assigning qualified staff to take over QA work.

81. On or about June 9, 2017, SOFIE's CTO Moore told Wilson, who oversaw the Sanford investigation and had dedicated 16 years to Zevacor (and its predecessors), that SOFIE had doubts about offering Wilson the position SOFIE had promised her, Vice President ("VP") of Quality, Regulatory and Environmental, Health and Safety (EHS) post-acquisition. Upon information and belief, Wilson did not have any prior performance problems.

82. In addition, SOFIE's President and CEO Phelps planned to fire Kraemer's boss, Zevacor COO Stagnolia, who also had extensive knowledge of the Sanford, Florida issues and was a decision-maker in pharmacist McCall's firing. Stagnolia chose to resign on September 21, 2017 (the official acquisition date).

83. After the acquisition, SOFIE failed to put in place a procedure or organizational structure for the QA team to report compliance issues and concerns. Before her firing, SOFIE instructed Kraemer's boss Wilson to report QA issues to Moore, Head of Operations, and not to President and CEO Phelps, as Phelps did not have time for QA issues and agendas.

84. SOFIE's policy of having QA report compliance issues to operations presents a conflict of interest that contravenes FDA regulations. Those regulations make clear that the QA unit must exist as a separate organizational entity to ensure that business/operational decisions do not interfere with the quality assurance of drug products.

85. On September 22, 2017, Moore confronted Wilson about the Sanford impurities investigation, and asked Wilson whether she had been coerced by Zevacor management (Webner and/or Stagnolia) into approving and signing the Sanford investigation report. Wilson responded that she was not coerced and explained that she agreed with the report's findings and with the corrective action Zevacor had taken, and vowed to take going forward, including firing McCall.

Kraemer Reports to SOFIE Compliance Failures and Malfeasance

86. On October 3, 2017, Kraemer complained to HR Director Smith about her HR and QA concerns, including her concerns about a recent SOFIE presentation. During SOFIE's presentation on October 2, 2017, CEO Phelps announced that "SOFIE will run the company with a 'Wild West' attitude"; the Powerpoint slide he presented featured a photograph of Phelps's father with a gun. Kraemer told Smith that SOFIE's mantra was deeply troubling: a commercial drug manufacturer and distributer cannot and should not run QA, which has very definitive rules and regulations, with a "Wild West" attitude. Moreover, SOFIE's presentation did not include a single slide or mention of QA or its role in the new company, which concerned Kraemer since QA plays an integral role in an FDA-regulated company.

87. Kraemer also expressed concern for her position in the new company, as SOFIE had reassigned Kraemer's reports to one of its own, Christopher Drake ("Drake"), who had

minimal, if any, experience in QA, and Kraemer no longer had a boss, since SOFIE had terminated Stagnolia's employment. Kraemer was also aware of the confrontations between Moore and Wilson and the possibility that Wilson would not continue in her current role as Head of QA/QA/EHS, another concern for the future of QA.

88. HR Director Smith told Kraemer there was little she could do to remedy these issues, as SOFIE CEO Phelps generally was not aligned with Smith, a Zevacor carryover.

89. On October 11, 2017, Smith called Kraemer to formally offer her the position Director of Pharmacy, Quality Assurance. Kraemer received and signed the offer letter from SOFIE that day. Pursuant to her employment agreement, Kraemer would now report to Wilson, "Interim Head Quality Assurance, Regulatory Affairs and EHS, HD-CO1QA."

90. SOFIE also provided Kraemer a new job description. According to this document, Kraemer's responsibilities included:

> Ensure compliance with USP [United States Pharmacopeia] <797>, <823>, proposed <825> regulations, or other state pharmacy requirements as applicable.[16]
>
> Provide feedback and support assistance to Pharmacists regarding customer satisfaction, new products or services offered, and potential new customers. Review and help coordinate ongoing pharmacy programs and implement continuous quality improvement programs that provide solutions for both SOFIE team members and customers. Work to resolve internal and external problems and implement solutions associated with providing pharmacy services. Assist sites in (internal or external) audits, as well any deficiencies found and corrective actions required.
>
> Provide training, guidance, coaching to all Professional Pharmacy employees.
>
> Act as QA support for new products introduced into the network, including, but not

[16] These chapters in the USP are applicable to Pharmacy, Sterile Compounding/Manufacturing and Radiopharmaceuticals. In her new role, Kraemer would have been ensuring that all of the pharmacies, pharmacists, pharmacy technicians and manufacturing sites were compliant with the guidance set forth in these chapters.

limited to, client audits as required.

Aid in other pharmacy related duties/projects as assigned.

Act as HIPAA compliance officer.

91. Despite offering Kraemer continued employment at the same level of compensation, SOFIE assigned Kraemer a diminished job title, and took away some of plaintiff's job responsibilities, including reassigning her direct reports to Drake, who was woefully inexperienced in QA.

92. Prior to the SOFIE takeover, Kraemer managed directly the QA and manufacturing aspects of Zevacor's relationship with Piramal. After the acquisition, SOFIE excluded Kraemer and the QA team from weekly calls with Piramal concerning FBB project action items. Kraemer and other QA staff were invited to attend only after Piramal's QA team made clear to Moore that SOFIE QA should be present on the calls. Prior to the acquisition, and in accordance with industry practice, QA is always included on status calls with contract manufacturing partners.

93. SOFIE also excluded the QA team from an important Senior Management Team conference that took place November 19-22, 2017 during which SOFIE set its agenda and strategy. Prior to the acquisition, QA team members were invited to such conferences, given QA's vital role within the company.

SOFIE Rehires McCall to a New Location

94. Also on the October 11, 2017 call with HR, Smith told Kraemer that SOFIE had instructed her to send an offer letter to McCall, the supervising pharmacist that Zevacor fired for cause based on his responsibility for the Sanford facility impurities.

95. Contrary to standard company practice, SOFIE never formally announced

McCall's rehiring.

96. In a further effort to hide this controversial action, including from the Florida Board of Pharmacy, SOFIE assigned McCall to its Kansas City facility. Like the Sanford facility, SOFIE also manufactures and distributes FBB in that facility.

97. Kraemer's first QA call with McCall took place on October 31, 2017. As it was Halloween, McCall joked that he was a "ghost" from Kraemer's past.

98. The Florida Board of Pharmacy showed up at the Sanford facility for an unannounced inspection on November 11, 2017. The inspection was a follow-up to the June 26 and August 21 letters Zevacor had sent to the Board concerning the FBB impurities. The inspection was handled by the facility's new site manager Keegan Flowers ("Flowers") and the newly-transferred nuclear pharmacist, Alex Freed ("Freed"), with remote support by Kraemer. During a follow-up call with Kraemer, Flowers and Freed told her that the Board of Pharmacy did not ask about McCall's status, and they did not disclose his rehire to SOFIE's Kansas City facility.

99. To make matters worse, perhaps because the Board of Pharmacy was no longer sniffing around, on information and belief, in or around June 2018, SOFIE put McCall back in charge of its Sanford, Florida facility.

100. On information and belief, SOFIE (and Piramal) should have, but did not, notify the Principal Investigator for the Alzheimer's IDEAS trial about the FBB doses with high impurities, leaving the nearly 40 affected patients with no way to know that they had been injected with potentially impure, toxic radioactive drugs.

101. Piramal and SOFIE also failed to inform the clinical trial patients who had

been injected with FBB containing non-complaint impurity levels. Under the National Institute of Health – Clinical Center Patient Bills of Rights ("NIH Patient Bill of Rights"),[17] clinical trial patients have a right to all medical information obtained during their participation in a clinical trial.

102. On November 10, 2017, Smith resigned from her HR Director position, citing as a reason for her decision SOFIE's firing of Brad Richardson ("Richardson"), the supervising pharmacist/site manager for defendant's Kansas City facility and McCall's rehiring in Richardson's place. After her resignation, Smith told Kraemer that SOFIE President and CEO Phelps asked her to manufacture a reason to fire Richardson so that SOFIE could place McCall in that position, notwithstanding his termination for egregious lapses in oversight at defendant's Sanford facility.

103. On November 17, 2017, Kraemer and other members of the QA team, including Wilson and SOFIE Regional Director Lynn Chwojdak ("Chwojdak"), participated in a wrap-up call for the Sanford Quality Audit that took place after the initial batch impurity investigation. Members of Piramal's QA team, Jeanette Brill and Samira Leesch, and Mok from the Piramal CMC team, and Drake from SOFIE also participated in the call. The Piramal QA representatives asked Kraemer and Wilson why SOFIE had rehired McCall, and specifically complained that SOFIE failed to inform Piramal about McCall's return. Kraemer responded that SOFIE senior management did not ask for QA input when it decided to rehire McCall, and even Kraemer and other QA staff at SOFIE were only notified after the fact.

104. Kraemer also felt a professional obligation to tell Piramal that SOFIE had

[17] https://clinicalcenter.nih.gov/participate/_pdf/bor.pdf.

placed McCall in its Kansas City facility, another manufacturing site for Piramal's FBB.

105. After the November 17 call with Piramal, Chwojdak emailed Kraemer to thank her for speaking up about McCall's questionable rehire. Chwojdak also expressed her own concerns about SOFIE's decision to rehire McCall, given his misconduct as head pharmacist of the Sanford facility. Thereafter, in March 2018, SOFIE took away Chwojdak's Regional Director title and demoted her to a site-level position.

106. Shortly after the November 17 call, Moore reprimanded Wilson, both orally and in writing, about Kraemer's disclosure to Piramal. Moore threatened Wilson, instructing her to "control her employees better." Wilson told Kraemer that Moore was referring to Kraemer when she made the threat.

107. Ten days later, on November 27, 2017, SOFIE fired Wilson for purported performance issues. Moore and SOFIE Chief Revenue Officer Phil Czernin ("Czernin") announced Wilson's firing to the QA team that day. Later the same day, defendant gathered the QA team again and stated that it had reviewed Wilson's emails and text messages and discovered inappropriate communications by Wilson. SOFIE revoked the severance package it had offered Wilson, based on her purportedly concerning emails and text messages. SOFIE however assured the remaining QA staff that their jobs were "safe."

108. During the meeting with QA, attended by Moore, Czernin and Zevacor QA carryovers Kraemer, Eugene Borelli ("Borelli"), Cristen Brown and Glenn Jennings, Moore and Czernin asked for an update on QA issues and about any other concerns that the group had. Kraemer reminded SOFIE of QA issues in the period leading up to SOFIE's takeover and expressed her concerns about QA's ability to function going forward, particularly given Wilson's abrupt firing

and the other employee departures. Kraemer was the only employee to voice her opinions and concerns during the meeting. Moore and Czernin did not respond.

Kraemer Reports Additional Regulatory Failures; SOFIE Retaliates and Fires Kraemer

109. Realizing that keeping on staff watchdogs like Kraemer was bad for business, and feeling confident that regulators were done investigating the Sanford impurities (and that most QA employees with knowledge of the compliance issues had resigned or were fired), SOFIE retaliated against Kraemer.

110. On November 28, 2017, Moore at the last minute pulled Kraemer and Borelli off an ongoing Johnson & Johnson audit in SOFIE's Somerset, New Jersey facility to attend a QA team call with Moore, purportedly to discuss outstanding QA concerns. Kraemer and Borelli were the lead SOFIE QA personnel handling the Johnson & Johnson audit, but were told by Moore the call with her was more important.

111. During this conference call, Kraemer, who was in New Jersey, told Moore about at least three regulatory and compliance issues that required SOFIE's immediate attention.

A. Kraemer Complains About Over-dispensing in Violation of Nuclear Regulatory Commission Regulations

112. In reviewing FBB prescriptions in the aftermath of the Sanford investigation, Kraemer noticed that SOFIE pharmacists had over-dispensed FBB doses in violation of the Nuclear Regulatory Commission ("NRC") Regulations (10 C.F.R. 35), i.e., that defendant's Sanford pharmacists were dispensing patient doses with greater radioactivity than the prescribing physician had ordered.

113. One of Kraemer's last emails to her now-fired boss Wilson, sent shortly before November 26, stated her plan to travel to the Sanford facility to investigate the over-dispensing, including compiling data across drug products to determine how far back the practice went, and to identify the pharmacists involved. Given McCall's role as head pharmacist and past misconduct and regulatory violations, Kraemer suspected that he was responsible.

114. During the November 28, 2017 call, Kraemer told Moore about the over-dispensing issue, her suspicions about McCall's involvement, and her plan to further investigate on-site.

115. Kraemer in the email to Wilson also stated her intention to report the over-dispensing to the NRC and the Florida Board of Pharmacy, in the event her suspicions were confirmed during the on-site audit.

116. Upon information and belief, SOFIE had access to Wilson's emails and had reviewed them prior to Kraemer's November 29 firing. (See ¶ 107, supra).

B. Kraemer Complains About Security Failures at SOFIE's Nuclear Pharmacies, including in New Jersey and Haverhill, Massachusetts, the Target of a Subsequent FDA Warning

117. Kraemer also told Moore that five of SOFIE's manufacturing facilities, including those in Haverhill, Massachusetts and Totowa and Somerset, New Jersey, were allowing pharmacy personnel to work in designated areas without a Registered Nuclear Pharmacist present. This practice violates Board of Pharmacy regulations in all states.

118. Kraemer also told Moore that, in contravention of FDA and Board of Pharmacy regulations, SOFIE did not have a working lock on the door to the restricted area or functioning facility alarms in its Haverhill facility. Kraemer told Moore that these security failures

could cause problems for SOFIE during an upcoming FDA or Board of Pharmacy inspection. In February 2018, the Haverhill facility was inspected by the FDA; on information and belief, the FDA flagged the security issues.

119. On September 27, 2018, the FDA issued SOFIE a "Warning Letter" for "significant violations of current good manufacturing practices" in its Haverhill facility.

120. Philip Nielson, R.Ph. ("Nielson") is the Pharmacist-in-Charge there.

121. After an FDA inspection, the FDA issues to the inspected site its "observations" of potential regulatory failures, and, for more serious issues, a citation called a 483. Both the observations and 483s are described in the FDA's Establishment Inspection Report ("EIR") that is issued to the site.

122. The inspection site thereafter has an opportunity to respond to/remedy the 483(s) in the EIR. It is best practice for the inspected site to also respond to the FDA's observations.

123. On information and belief, after SOFIE received the EIR for the Haverhill facility, which listed specific compliance failures by Pharmacist-in-Charge Nielson, SOFIE promoted him to Kraemer's former position.

124. This was not Nielson's first run-in with the FDA. On information and belief, during an FDA inspection of another SOFIE/Zevacor facility, Nielson was reprimanded for his conduct that breached sterile lab environmental regulations.

125. Apparently, SOFIE's response to the FDA's EIR fell woefully short. The

FDA issued SOFIE a "Warning Letter" for regulatory violations at its Haverhill facility on September 27, 2018; the FDA expressly rejected as "inadequate" each and every corrective action that SOFIE claimed to have taken to remedy the violations.

126. The FDA's Warning Letter states, "Because your methods, facilities, or controls for compounding, processing, packing, or holding do not conform to CGMP [current good manufacturing practice], your PET drug products are adulterated within the meaning of section 501 (a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(C)."

127. SOFIE manufactures FBB in the Haverhill facility.

128. The violation that the FDA flagged – adulterated drugs, including FBB – was the very problem that Kraemer reported at SOFIE's Sanford, Florida facility.

129. The FDA cited the following non-exhaustive list of compliance failures by SOFIE: (1) bacterial contamination of an injectable product batch that SOFIE released (violation of 21 CFR 212.20 (d)); (2) the Haverhill facility was "in a state of disrepair and lacked cleanliness" and was thus inadequate to "ensure prevention of contamination of equipment or product by environmental conditions that could reasonably be expected to have an adverse effect on product quality" (violation of 21 CFR 212.30(a)); and (3) changing manufacturing processes without "adequately manag[ing] th[e] change to ensure that it would not adversely affect the identity, strength, quality, or purity of [SOFIE's] PET drug prior to being implemented" (violation of 21 CFR 212.20(c)).

C. Kraemer Reports HIPAA Violations

130. Finally, during the November 28, 2017 meeting, Kraemer told Moore about

issues with SOFIE's HIPAA non-compliance.

131. As Kraemer's job description reflects, she was SOFIE's designated HIPAA compliance officer.

132. Kraemer informed Moore that SOFIE failed to display required employee postings on HIPAA; SOFIE's customers were being allowed to email patient prescriptions to pharmacies (including orders for clinical trials which require patient anonymity) through non-encrypted pathways; and original SOFIE employees had yet to take the required HIPAA training.

SOFIE Fires Kraemer in Retaliation for Her Reports

133. Just one day later, on November 29, 2017, SOFIE fired Kraemer.

134. During the firing meeting in New Jersey attended by Kraemer, Moore and Czernin, SOFIE told Kraemer that it had reviewed her text message communications with Wilson and discovered a message in which Kraemer allegedly physically threatened Moore. This is false.

135. Kraemer is aware of other SOFIE (including former Zevacor) employees who had not engaged in protected activities, who exchanged unprofessional communications and were not fired or otherwise disciplined as a result.

136. For example, SOFIE President and CEO Phelps orally warned employee Bernard Lambert ("Lambert") about his inappropriate text messages but did not otherwise take any action against him.[18]

137. Darren Patti ("Patti"), a current SOFIE Regional Director, was questioned

[18] Lambert voluntarily resigned from SOFIE on or about December 1, 2017.

by Moore as to why all of his text messages to Wilson were erased, but SOFIE did not attempt to recover them. Wilson told Kraemer that Patti had sent her multiple inappropriate text messages and emails laden with profanities, in which Patti expressed his concerns about the future of the Company; criticized Moore's decision-making abilities; and disagreed with SOFIE's decision to rehire McCall and, relatedly, complaining about becoming McCall's direct report. On information and belief, Patti was not disciplined, let alone fired, for these communications.

138. SOFIE also falsely claimed that Kraemer breached confidentiality by asking an outside HR professional for advice on how to escalate her concerns, given that Smith had told Kraemer that she could not assist her with any recourse because SOFIE executives refused to work with Smith. Kraemer did not disclose any confidential or proprietary information in these communications. SOFIE's allegation of breach of confidentiality is pretext for retaliation; indeed, SOFIE in July 2017 disclosed externally the purportedly confidential Sanford report.[19]

139. At the end of the firing meeting, Moore offered to give to potential employers a positive reference for Kraemer.

140. Kraemer's firing letter states as the reason for her dismissal SOFIE's "discovery of potentially defaming and unprofessional electronic communications concerning SOFIE and its management disseminated by you."

141. The severance agreement SOFIE offered Kraemer contains a broad release of legal claims against SOFIE "its respective parents, subsidiaries, divisions, affiliates,

[19] On July 10, 2017, Piramal QA representative Mok told Wilson that SOFIE had shared the confidential June 26, 2017 Sanford report with Dr. Daniel Yokell of MGH-Massachusetts General Hospital, Head of PET production Chemistry & PET Nuclear Pharmacy Services.

shareholders, officers, directors, agents, employees, predecessors, successors, and assigns[,]" including for whistleblower retaliation under federal, state and local law. Unwilling to waive her rights or to remain silent about SOFIE's unlawful conduct, Kraemer refused to sign the severance agreement.

142. SOFIE's offering Kraemer a positive job reference and severance package contradicts its claim that plaintiff was fired for cause and reveals it for the pretext that it is.

143. Before Kraemer reported her concerns about regulatory violations, including the multiple adulterated doses of FBB that had been injected into clinical trial patients paying top dollar for the drug, Kraemer had received only positive performance reviews and incentive compensation.

144. Shortly after her November 29, 2017 firing, Kraemer learned that SOFIE defamed her to members of the QA and Technical Development teams. Specifically, Moore claimed falsely that Kraemer was fired because she physically threatened Moore, including, by stating, "Tie up [Melissa Moore] and kill the bitch."

FIRST CAUSE OF ACTION
(CEPA Retaliation)

145. Plaintiff repeats and realleges paragraphs 1 through 144 as if fully set forth herein.

146. Plaintiff complained about or objected to SOFIE's activities, policies, and/or practices that she reasonably believed were in violation of a law, rule, or regulation, including, inter alia, pervasive practices that violated FDA and state Board of Pharmacy regulations, HIPAA,

and federal good manufacturing practice regulations.

147. Plaintiff also complained about or objected to SOFIE's activities, policies, and/or practices that she reasonably believed were incompatible with a clear mandate of public policy concerning the public health, safety or welfare, mainly ensuring that clinical trial patients are treated with compliant drugs and are fully informed about their treatment.

148. By the acts and practices described above, defendant retaliated against plaintiff on the basis of her protected activities in violation of CEPA.

149. Defendant acted with malice and reckless indifference to plaintiff's rights under CEPA.

150. As a result of defendant's retaliation, plaintiff has suffered and will continue to suffer irreparable injury, emotional distress, and other compensable damages unless and until this Court grants relief.

SECOND CAUSE OF ACTION
(Defamation)

151. Plaintiff repeats and realleges paragraphs 1 to 150 of the Complaint as if fully set forth herein.

152. Defendants falsely stated to plaintiff's former coworkers, including members of SOFIE's QA and Technical Development, that plaintiff was fired because she physically threatened SOFIE CTO Melissa Moore, including, that plaintiff said, "Tie up [Melissa Moore] and kill the bitch." Kraemer never threatened Moore, let alone did she make the violent, explicit threat that SOFIE attributed to her.

153. Defendant knowingly made about plaintiff such false statements or made such statements in reckless disregard of their truth or falsity. Defendant's statements that falsely

charged plaintiff with making violent threats against a Company executive tended to harm plaintiff's reputation in the eyes of the community or to cause others to avoid plaintiff.

154. Defendant defamed plaintiff by slander per se by making false statements that adversely reflected on plaintiff's fitness as a pharmacist and quality assurance professional. Defendant's slanderous statements have exposed plaintiff to contempt, ridicule, and disgrace.

155. Defendant also defamed plaintiff by slander, causing damage to her reputation, including her professional reputation.

156. Defendant made the defamatory statements with malice.

157. Plaintiff has suffered and will continue to suffer compensable damages, including but not limited to, damage to her reputation, unless and until this Court grants relief.

PRAYER FOR RELIEF

WHEREFORE, plaintiff respectfully requests that this Court enter a judgment:

(a) declaring that the acts and practices complained of herein are in violation of CEPA and New Jersey common law;

(b) enjoining and permanently restraining these violations;

(c) directing defendant to take such affirmative action as is necessary to ensure that the effects of these violations are eliminated and do not continue to affect plaintiff's employment opportunities;

(d) directing defendant to place plaintiff in the position she would have occupied but for defendant's retaliatory treatment of her, and to make her whole for all earnings she would have received but for defendant's retaliatory treatment, including but not limited to, wages, pension, interest, and other lost benefits;

(e) directing defendant to pay plaintiff compensatory damages for her mental anguish, emotional distress, and humiliation;

(f) directing defendant to pay plaintiff punitive damages;

(g) awarding plaintiff pre- and post-judgment interest;

(h) awarding plaintiff the costs of this action together with reasonable attorneys' fees; and

(i) granting such other and further relief as this Court deems necessary and proper.

DEMAND FOR A TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, plaintiff demands a trial by jury in this action.

Dated: New York, New York
November 20, 2018

VLADECK, RASKIN & CLARK, P.C.

By: _____

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